(c) The Director and Deputy Director, Division of Drug Quality Evaluation, Office of Compliance, CDER.

(d) The Chief and Assistant Chief, Product Surveillance Branch, Division of Drug Quality Evaluation, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989]

§ 5.74 Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 506 of the Federal Food, Drug, and Cosmetic Act regarding the issuance, amendment, or repeal of regulations pertaining to drugs containing insulin:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989]

§ 5.75 Designation of official master and working standards for antibiotic drugs.

The following officials are authorized to designate official Food and Drug Administration master and working standards for antibiotic drugs under § 430.5 of this chapter:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Research Resources, CDER.

(c) The Director and Deputy Director, Division of Research and Testing, Office of Research Resources, CDER.

[49 FR 27315, July 3, 1984, as amended at 54 FR 8319, Feb. 28, 1989]

§ 5.76 Certification of antibiotic drugs.

The following officials are authorized to certify or reject batches of antibiotic drugs, or any derivative of these drugs, pursuant to sections 507(a) and 512(n) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Compliance, CDER.

(c) The Director and Deputy Director, Division of Drug Quality Evaluation, Office of Compliance, CDER.

(d) The Chief and Assistant Chief, Product Surveillance Branch, Division of Drug Quality Evaluation, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989]

§ 5.78 Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 507 of the Federal Food, Drug, and Cosmetic Act (the act) regarding the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use:

(1) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Compliance, CDER.

(b) The Director and Deputy Director, Center for Devices and Radiological Health, are authorized to perform all the functions of the Commissioner of Food and Drugs under section 507 of the act regarding the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use contained in medical devices.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14935, Apr. 16, 1984; 54 FR 8319, Feb. 28, 1989]

§ 5.80 Approval of new drug applications and their supplements.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act:

(i) The Director and Deputy Director, and Deputy Director (Medical and

Scientific Affairs), Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I and Drug Evaluation II, CDER, for drugs under their jurisdiction.

(iii) The Director, Office of Over-the-Counter Drug Evaluation, CDER, for drugs under the Director's jurisdiction.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), for drugs listed in §314.440(b) of this chapter, are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act.

(b) The officials listed in paragraphs (b) (1) and (2) of this section, for drugs under their jurisdiction, are authorized to perform all functions of the Commissioner of Food and Drugs with regard to approval of supplemental applications to approved new drug applications for drugs for human use that have been submitted under §314.70 of this chapter and of new drug applications for drug products other than those that contain new molecular entities (new chemical entities). The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in §5.10(a) and paragraph (a) of this section.

(1) The Directors and Deputy Directors of the divisions in the Office of Drug Evaluation I, CDER.

(2) The Directors and Deputy Directors of the divisions in the Office of Drug Evaluation II, CDER.

(c) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of abbreviated new drug applications and supplements thereto for drugs for human use and new drug applications for drugs with a 5S classification whose clinical safety and efficacy may be supported by appropriate literature citations in lieu of submission of data from original proprietary studies, or 505(b)(2) applications under their jurisdiction. The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in §5.10(a) and paragraph (a) of this section.

(1) For drugs submitted under §§314.50, 314.70, and 314.94 of this chapter, except for those drug products listed in §314.440(b):

(i) The Director and Deputy Director, Office of Generic Drugs (OGD), CDER, except that the Director and Deputy Director, OGD are not authorized to approve new drug applications with a 5S classification if clinical studies are needed.

(ii) The Directors and Deputy Directors of the divisions in the Office of Drug Evaluation I, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Office of Drug Evaluation II, CDER.

(iv) The Director, Pilot Drug Evaluation Staff, CDER.

(2)(i) For drug products listed in §314.440(b) and submitted under §§314.50, 314.70, and 314.94 of this chapter:

(ii) The Director and Deputy Director, Office of Biological Product Review, CBER.

(d) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or 505(b)(2) applications for drugs for human use that are described in §314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. Authority to approve supplements that require in vivo bioavailability studies or that include in vivo bioavailability study waiver requests are not included in this paragraph.

(1) The Director and Deputy Director of the Division of Chemistry I, OGD.

(2) The Director and Deputy Director of the Division of Chemistry II, OGD.

(3) The Associate Director for Chemistry, OGD.

(e) The Director and Deputy Director, Division of Labeling and Program Support, OGD, are authorized to perform all the functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or 505(b)(2) applications for drugs for human use that

are described in §314.70(b)(3) and (c)(2)(i) through (c)(2)(iv) of this chapter. Authority to approve supplements that require in vivo bioavailability studies or in vivo study waiver requests is not included in this paragraph.

(f) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to new drug applications for drugs for human use that are described in §314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. Authority to approve supplements that require in vivo bioavailability information or that require a change in the labeling of the drug, except changes that reflect only the use of a different facility or establishment, are not included in this paragraph. The supplemental applications to which this authorization applies may continue to be acted upon by the officials so authorized in §5.10(a) and paragraphs (a) and (b) of this section.

(1) The supervisory chemists in the divisions in the Office of Drug Evaluation I, CDER.

(2) The supervisory chemists in the divisions in the Office of Drug Evaluation II, CDER.

[49 FR 14935, Apr. 16, 1984, as amended at 50 FR 30697, July 29, 1985; 50 FR 47207, Nov. 15, 1985; 52 FR 37764, Oct. 9, 1987; 54 FR 8319, Feb. 28, 1989; 55 FR 6247, Feb. 22, 1990; 55 FR 51688, Dec. 17, 1990; 57 FR 17980, Apr. 28, 1992; 58 FR 17094, Apr. 1, 1993; 59 FR 33431, June 29, 1994; 60 FR 57338, Nov. 15, 1995]

§5.81 Responses to Drug Enforcement Administration temporary scheduling notices.

The Associate Commissioner for Health Affairs is authorized to provide responses to the Drug Enforcement Administration's temporary scheduling notices under the Controlled Substances Act, as amended (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 811(h)(4), as amended hereafter). The delegation excludes the authority to submit reports to Congress.

[60 FR 54424, Oct. 24, 1995]

§5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

(a) The Director and Deputy Director, Center for Drug Evaluation and Research, are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use, except for those drugs listed in §314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research, for those drugs listed in §314.440(b) of this chapter, are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

[54 FR 8319, Feb. 28, 1989]

§5.83 Approval of new animal drug applications and their supplements.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of new animal drug applications, and supplements thereto, for new animal drugs submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to approved new animal drugs submitted pursuant to section 512 of the act: